Public Information: Advance Notice of the FDA Structured Product Labeling Project - Request for Information

General Information

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General Services Administration, Federal Technology Service (FTS), Federal Systems Integration & Management Center (TFM), 6354 Walker Lane Suite 200, Alexandria, VA, 22310

Description

The GSA Federal Systems Integration and Management Center (FEDSIM) on behalf of the Food and Drug Administration plans to release a Request For Information (RFI) for the Structured Product Labeling (SPL) Project. The overall objective of the FDA Structured Product Labeling project is to create a technological environment that will enable FDA to reliably generate up-to-date SPL for all drug products marketed in the United States. (Future phase can potentially concentrate on other FDA-regulated products including vaccines, animal drug products, dietary supplements and medical devices.) SPL contains the following medication information: (1) How to use medication – dosing recommendations and monitoring use; (2) When to use medication – indication, clinical effects (e.g., interactions and adverse events), activity (e.g., mechanism of action), other information about the use of the medication; (3) Description of the medication – names, ingredients, strength, appearance, dosage form; (4) How the medication is supplied – name, package type, quantity; and (5) Distributor of the medication. Achieving this objective will require changes to existing regulations, development of standards, creation of computer systems, training and education inside and outside of FDA, improvements to the current processes for the review and approval of labeling changes and improvements to the current processes for data entry and quality control of drug listing. Purpose: The purpose of the SPL RFI will be to assist the Food and Drug Administration in identifying possible technical alternatives that will assist in developing Computer Systems. SPL RFI Release Date: October 15, 2004. RFI Responses will be due by October 29, 2004. For more

information, visit the following web site: http://www.fda.gov/oc/datacouncil/spl.html This web site contains links to SPL Guidance, Implementation Guide (draft), and other pertinent information. http://www.fda.gov/OHRMS/DOCKETS/98fr/03-30641.pdf "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format"; http://www.fda.gov/OHRMS/DOCKETS/98fr/04-2536.htm "Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format--Content of Labeling; Availability"

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